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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,865	02/07/2005	Hideko Kosaka	10921.0278USWO	1872

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EXAMINER	
GERIDO, DWAN A	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
08/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,865	KOSAKA, HIDEKO	
	Examiner	Art Unit	
	Dwan A. Gerido, Ph.D.	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-7-2005, 10-16-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 5, 6, 8, 9, 12, 13, 14, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Proffitt et al., (US 2005/0106748).

3. For claims 1, 8, and 13 Proffitt et al., teach a method of using a protein assay indicator wherein the indicator has an identical structure and substituent groups as that of the instant claims. Specifically, Proffitt teaches X1 and X2 as halogens, X3 as a hydrogen, X4 as a hydroxyl group, and X5 as a salt of a carboxyl group (paragraph 0040, structure B.

4. For claims 2, 9 and 14 Proffitt et al., teach X1 and X2 as bromine, and X3 being a hydrogen (paragraph 0040, structure B).

5. For claims 5, 12, and 17, Proffitt et al., teach utilizing dyes identical to those of the instant application, namely eosin B, eosin Y, rose bengal, and phloxine B (paragraph 0038), which would exhibit identical properties as stated in the instant claims.

6. For claim 6, Proffitt et al., teach albumin as the protein to be measured (paragraphs 0092, 0097).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3, 10, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al., (US 2005/0106748).

10. With regards to claims 3, 10, and 15, Proffitt et al., teach a method of assaying proteins using the compound of the instant claims wherein X1 and X2 are Bromine or Iodine (paragraphs 0040, 0041, structures B and C). Proffitt et al., do not explicitly teach X3 as chlorine. However, Proffitt et al., do recite utilizing halogenated alkyl substituent groups to increase solubility of an organic compound in aqueous solutions (paragraph 0036). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Proffitt et al., to include halogenated alkyl groups in order to increase solubility of the assay indicator in aqueous solutions. In addition, the MPEP recites that when substituting one element for another known in the field, the combination must do more than yield a predictable result. Therefore, it

would have been obvious to utilize any halogen such as chlorine as substitution requires only routine skill in the art.

11. Claims 4, 11, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al., (US 2005/0106748) in view of Sujeeth (US 5,772,696).

12. With regards to claims 4, 11, and 16, Proffitt et al., do not explicitly teach the assay indicator wherein sodium is bound to the hydroxyl and carboxyl groups.

Sujeeth teaches a process for purification of water soluble dyes utilizing an organic molecule of identical structure (eosin Y) as that of the instant claims wherein sodium is bound to the hydroxyl and carboxyl groups (column 5 lines 30-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Proffitt et al., in view of Sujeeth et al., to bind sodium to make a salt in order to increase the water solubility of the compound and measure albumin in normal human ranges of 10-20mg/dl respectively.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al., (US 2002/0106748) in view of Lau (EP 0,361,244).

14. With regards to claim 7, Proffitt et al., do not teach measuring an albumin concentration between 10 and 20 mg/dL.

Lau teaches a method of assaying urinary albumin wherein the normal concentration of urinary albumin is between 10 and 20mg/dL. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffitt et al., in view of Lau in order to determine renal abnormalities due to increased or decreased urinary protein levels.

15. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al., (US 2005/0106748) in view of Bullard et al., (US 3,963,442).

16. With regards to claim 18, Proffitt et al., do not teach a sensitizer for coloration sensitivity within the test piece.

Bullard et al., teach a colorimetric indicator wherein colorimetric indicators sensitive to pH are placed in the test sheet (column 8 lines 47-49, table II). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the test strip of Proffitt et al., with the sensitizer of Bullard et al., in order to provide colorimetric means of verifying pH of the solution.

17. With regards to claim 19, Bullard et al., teach polyethylene glycol as a colorimetric sensitizer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the test strip of Proffitt et al., with the polyethylene glycol sensitizer of Bullard et al., in order to provide a water soluble sensitizer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797
DAG